UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | ) | MDL No. 1456 |
| THIS DOCUMENT RELATES TO: | ) | Civil Action No. 01-12257-PBS |
| *United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS. | ) | Subcategory No. 06-11337-PBS<br>Hon. Patti B. Saris |

**MEMORANDUM IN SUPPORT OF UNITED STATES' MOTION IN LIMINE TO PRECLUDE EVIDENCE OF "GOVERNMENT KNOWLEDGE" AS IRRELEVANT TO FALSITY, SCIENTER, CAUSATION OR DAMAGES UNDER THE FALSE CLAIMS ACT**

After years of exhaustive discovery of the Department of Health and Human Services (HHS), specifically the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG), Dey cannot point to a single document or federal witness authorizing Dey or any drug manufacturer to report average wholesale prices (AWPs) that had no connection to actual prices in the market.[1] Nor can Dey point to any public pronouncement or communication from the United States on which Dey relied when it set and reported false AWPs.

Undeterred by the absence of any such evidence, let alone a "smoking gun," Dey intends to introduce an array of OIG reports and testimony from (primarily former) CMS employees in an attempt to show that the government understood AWPs were inflated and somehow "decided"

[1] The extent of discovery on this issue was monumental: including over fifty depositions of federal witnesses, production of over 600,000 pages of documents, and extensive briefing on numerous motions seeking to compel additional production.

– through a tacit, nonpublic policy – to acquiesce in certain drug manufacturers' practice of reporting inflated prices.[2] Dey's proffered evidence, however, does little more than document both OIG's and CMS's growing awareness of the increasing discrepancy between reported AWPs and actual transaction prices, and incremental recognition that drug manufacturers' gaming of the AWP-based Medicare reimbursement system was making it unworkable. This evidence has no place in a False Claims Act ("FCA") trial, because it is not relevant to any element or defense under the FCA. Moreover, such evidence carries with it great potential to confuse the jury given that this Court already rejected defendants' "term of art" argument, based in large part on Congress's commitment to paying "reasonable" reimbursement for drugs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 285 (D. Mass. 2006). In affirming this decision, the First Circuit likewise recognized "Congress's unwavering commitment to the overarching policy that Medicare reimbursement should be reasonable and reflective of acquisition costs." 582 F.3d 156, 171 (1st Cir. 2009). Accordingly, the "government knowledge" evidence should be excluded under Fed. R. Evid. 402 and 403.

### A. OIG Reports On Medicare Drug Reimbursement and Testimony of HHS Employees on AWP Are Not Relevant to Any Element or Valid Defense Under the FCA

Under 31 U.S.C. § 3729(a)(1), the United States must prove that (a) the defendant presented or caused to be presented a false or fraudulent claim for payment, (b) the defendant acted "knowingly," and (c) the falsity was material. To recover damages, the United States must prove the loss was sustained "because of the act" of the defendant. *See Massachusetts v. Mylan*

[2] It also appears that Dey will seek to introduce such evidence through two of its experts, Dr. W. David Bradford and Dr. Lauren J. Stiroh. The United States has filed motions in limine to exclude such testimony by both experts.

*Labs.*, 608 F. Supp. 2d 127, 139 (D. Mass. 2008).

For the time period at issue here, 1993 to 2003, reimbursement for the subject drugs (albuterol and ipratropium bromide) was governed by regulation and/or statute that based reimbursement on the median "average wholesale price."[3] Both this Court and the First Circuit have rejected defendants' argument that AWP was an industry term of art for an undiscounted list price that had no predictable relationship to transaction prices. Instead, both Courts have construed the reporting of AWPs that gave no indication of the substantial discounts provided in the market as contrary to Congress's intent in designing the Medicare program. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 287-88, *aff'd*, 582 F.3d at 171.

Dey seeks to avoid liability for its reporting of false prices by introducing evidence of the government's knowledge that many reported AWPs were inaccurate, such as OIG reports on Medicare overpayments for Part B drugs.[4] Similarly, its designations of witnesses and deposition testimony indicate Dey intends to offer testimony by former HHS employees as to their personal understanding of what the term AWP meant in terms of reported prices -- for

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[3] From 1992 through 1997, the federal regulation at 42 C.F.R. § 405.517 provided that, for multiple-source drugs such as these, payment was based on "the lower of the estimated acquisition cost . . . or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." 56 Fed. Reg. 59,502, 59,621 (Nov. 25, 1991). The Balanced Budget Act of 1997 modified this payment scheme to require, beginning January 1, 1998, that payment be based on 95% of the median AWP for the drug. Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o); *see* 42 C.F.R. § 405.517 (1998). *See generally In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 164-67.

[4] For example, Dey's exhibit list identifies as "expect to use" exhibits the 1996 HHS OIG report "Medicare Payments for Nebulizer Drugs" (OEI-03-94-00390) (Dey Trial Ex. 6801); the 1997 OIG report "Excessive Medicare Payments for Prescription Drugs" (OEI-03-97-00290) (Dey Trial Ex. 7073); and the 1998 OIG Report "Are Medicare Allowances for Albuterol Sulfate Reasonable?" (OEI-03-97-00292) (Dey Trial Ex. 7193), among others. *And see* Dey Trial Ex. 7555 (June 2000 OIG report – Medicare Reimbursement of Albuterol (OEI-03-00-00311)); Dey Trial Ex. 8107 (March 2002 OIG Report - Excessive Medicare Reimbursement for Albuterol (OEI-03-01-00410); Dey Trial Ex. 8108 (OIG Report - Excessive Medicare Reimbursement for Ipratropium Bromide (OEI-03-01-00411)).

example, that some came to think of it as a "list price." As shown below, this evidence is not relevant to any FCA element or valid defense, but instead seems plainly calculated to invite the jury to conclude that AWP was in fact an industry term of art for an undiscounted "sticker price" – contrary to this Court's and the First Circuit's rulings. To admit such evidence would allow an unlawful practice to become the basis of a defense simply because it was widespread and one agency was able to investigate the falsity more nimbly than another branch of government (Congress) could assess and implement steps to protect the reimbursement system from being exploited. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 171 (finding "the legislative history and statutory context to be one of slow adaptation to shadowy industry practices, not ratification of them."). As explained below, this is not a proper issue for the jury in an FCA case.

1. The Evidence is Irrelevant to Falsity

Dey's so-called "government knowledge" evidence has no tendency to make it more or less probable that Dey's reported AWPs were "false." *See* Fed. R. Evid. 401. There is no doubt that Dey's reported AWPs did not resemble actual prices. Under prior rulings by this Court and the First Circuit construing the meaning of AWP in the context of Medicare reimbursement, defendants' reported AWPs are false as a matter of law. To allow Dey, for the purpose of deciding falsity, to present evidence of the government's developing knowledge that many AWPs were inflated would invite the jury to decide that AWP means exactly what this Court and the First Circuit have held it does not mean. As observed by the Ninth Circuit, the "meaning [of Federal regulations] is ultimately the subject of judicial interpretation, and it is [defendant's] compliance with [the] regulations, as interpreted by this court, that determines whether its

[conduct] resulted in the submission of false claims under the [False Claims] Act." *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999).[5] Furthermore, even if there were an open question about the meaning or intent of the federal regulation and statute, reference would be exclusively to the official public record. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004), *cited in In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 167-68. As *Lachman* makes clear, personal opinions by agency staff are irrelevant to the issue of determining regulatory intent. In sum, the evidence at issue is not admissible with respect to the falsity of Dey's reported AWPs.

2. The Evidence at Issue Is Irrelevant to Whether Dey "Caused" False Claims to Be Presented

There are two types of causation at issue in this case: liability causation and damages causation. Liability causation under the FCA turns on whether the defendant "causes to be presented, a false or fraudulent claim," or knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1), (a)(2) (now appearing at § 3729(a)(1)(A) and (a)(1)(B)). Damages causation relates to whether the government sustained damages "because of the act of that person." 31 U.S.C. § 3729(a). Dey contends that evidence of government knowledge is relevant to liability causation because it shows that the government, not Dey, caused inflated claims to be submitted.

Unable to point to anything actually passed by Congress or promulgated by HHS, Dey suggests there was some unwritten agency policy to use inflated AWPs controlled by

[5] Nor can defendants be permitted to present evidence or argue that some understandings on the part of some government employees constituted a *de facto* modification of either the governing statute or regulation. In contrast to a government contract, which may in limited circumstances be modified by the contracting officer, neither legislation nor regulations may be altered in such an ad hoc fashion.

manufacturers to set Medicare payments in order to cross-subsidize inadequate pharmacy dispensing fees and ensure beneficiary access.[6] To the extent Dey presses this argument as to damages, it is addressed below. But insofar as this argument is raised as a defense to liability, it is nonsensical. The idea that the Medicare program or any government employee caused Dey to report false AWPs or providers to submit inflated claims for reimbursement turns logic on its head. Dey set and reported the false AWPs, not Medicare. Dey did so knowing that its customers would seek payment from Medicare based on the false AWPs. Moreover, the plain import and explicit conclusion of the OIG reports is that inflated drug payments resulting from false AWPs were perceived as a problem by both CMS and OIG. No court has held that the United States is estopped from bringing an FCA action because it did not amend or abandon a program that was susceptible to fraud and abuse. *See Mylan Labs.*, 608 F. Supp. 2d at 152 (state's failure to use AMPs to "reverse engineer" actual prices "does not equate to government knowledge or approval"); *In re Lupron Marketing and Sales Practices Litig.*, 295 F. Supp. 2d 148, 162-63 (D. Mass. 2003) (rejecting the argument that Congress had "repeatedly, consciously, and intentionally left the current [AWP-based] system in place [and] the inescapable conclusion that Congress intend[ed] AWP to be higher than the cost charged to providers" and finding that "the suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual"). There is simply no basis for arguing that the evidence Dey seeks to introduce bears on liability causation under the FCA.

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[6] *See* Combined Memorandum of Defendants Abbott Laboratories Inc., Dey, Inc., Dey, L.P., Dey L.P., Inc., Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc. In Opposition to the United States' Cross-Motions for Partial Summary Judgment (Master Dkt #6429, Sub. #409), at pp. 33-34.

3. The Evidence Is Not Probative as to Whether Dey Acted "Knowingly"

The Court is familiar with the regulatory history of the 1991 regulation, the various OIG reports, and other evidence indicating that, over time, CMS employees became increasingly aware that published AWPs often did not accurately or consistently reflect the prices at which products were available in the marketplace. Yet, after years of intense discovery, Dey can point to no contemporaneous evidence that its employees, including those responsible for setting and reporting AWPs to the pricing compendia, even looked at any of this information, let alone relied upon it, when setting and reporting AWPs. In addition, there is no evidence indicating that Dey ever explained its price reporting practices to the federal government, and certainly none that any federal official told any Dey employee that its price reporting practices were acceptable or lawful.

The defendant employees responsible for setting Dey's AWPs did not read or rely upon any of the government reports Dey now points to in order to avoid liability. *See* United States' 56.1 Statement of Undisputed Material Facts As to Dey (Dkt. 6432, Sub. 411) (US-SOF-D), ¶¶ 180-99.[7] Later testimony from federal officials obviously was not even available to Dey at the time Dey set and reported inflated prices to the compendia. Accordingly, such evidence has

[7] Dey designated Pamela Marrs to testify on its behalf regarding Dey's professed belief that the United States government approved of or acquiesced in Dey's price reporting. US-SOF-D, ¶¶ 180-81. Ms. Marrs was not able to identify a single Dey employee who read or relied upon any government report in setting AWPs. *Id.*, ¶¶ 187-88. Nonetheless, Ms. Marrs testified that she believes the government approved of Dey's price reporting practices based on communications with counsel. Dey refused, however, to disclose the content of such communications because they were privileged. *Id.*, ¶¶ 195-96. Having refused to disclose in discovery the advice of counsel it professes to have relied upon, Dey cannot claim reliance on advice of counsel at trial. *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 24 (1st Cir. 2003) (client cannot claim reliance on advice of counsel and then assert privilege as to lawyer's advice); *United States v. Mubayyid*, 2007 WL 2475872, * 5 (Aug. 6, 2007 D. Mass.) (same).

no bearing on whether Dey acted "knowingly" when it reported false AWPs. The plain language of the FCA's definition of "knowing" puts the focus on what the *defendant* knew or ignored, not on what the government knew.[8] *See, e.g., United States v. Newport News Shipbuilding Inc.*, 276 F. Supp. 2d 539, 564 (E.D. Va. 2003) (observing that a defendant's disclosure to the government of the true facts might establish that the defendant did not knowingly submit a false claim), *quoted with approval in Massachusetts v. Mylan*, 608 F. Supp. 2d at 149; *see also United States ex rel. Irwin v. Significant Educ., Inc.*, 2009 WL 322875 at *2 (D. Ariz. Feb. 10, 2009) (disregarding government publication belatedly cited by defendant as justification for action in part because defendant never showed reliance on publication); Michael J. Davidson, *The Government Knowledge Defense to the Civil False Claims Act: A Misnomer by Any Other Name Does Not Sound as Sweet*, 45 Idaho L. Rev. 41, 56 (2008) ("Interpreting the FCA to provide an absolute defense based on government knowledge of the specific falsity at issue, without a concomitant effect on the defendant's mental state, would lead to absurd results.").

FCA case law consistently points to evidence of some interaction between the defendant and government employees as the key factor in weighing the knowledge element of the FCA. *See United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 327 (9th Cir. 1995) (where the defendant and the government "so completely cooperated and shared all

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[8] Section 3729(b)(1) of the FCA, 31 U.S.C., provides,

> the terms "knowing" and "knowingly" --
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> (A) mean that a person, with respect to information--
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> (i) has actual knowledge of the information;
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> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
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> (iii) acts in reckless disregard of the truth or falsity of the information; and
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> (B) require no proof of specific intent to defraud

information," defendants' claims were not knowingly false); *United States ex rel. Stebner & Stephenson Servs.*, 144 Fed. App. 389, 394, 2005 WL 1865309 (5th Cir. 2005) (unpublished) ("The Government was involved in the design, production, testing, and modification of the FMTVs; and [the defendants] and the Government negotiated contract modifications in response to the well-documented corrosion problem."). Similarly, in a criminal tax case, the First Circuit held that evidence of government publications was properly excluded where defendants failed to lay a foundation or offer proof linking the evidence to defendant's scienter:

> The evidence at issue here . . . [a Federal Register publication, and the Tax Code] . . . . would have been relevant only insofar as they supported other evidence offered to negate the element of willfulness, for example, testimony that Lussier knew of the 1946 regulation and relied on it when he decided not to file a tax return, or that he attempted to consult the tax code and was led astray by its bulk and confusing language. But no evidence to that effect was introduced or proffered. Absent such a foundation, the exhibits could only have confused the jury.

*United States v. Lussier*, 929 F.2d 25, 31 (1st Cir.1991); *see also United States v. St. Pierre*, 599 F.3d 19, 22 (1st Cir. 2010) (observing that a judge "has wide latitude in administering Rule 403," and affirming the exclusion, on the basis of potential to confuse and mislead the jury, of evidence of accounting standards that were "unknown" to the defendant at the time of the conduct at issue). Here, because Dey officials were oblivious to OIG reports and deposition testimony only obtained years later in this litigation, the evidence should be excluded.

In any event, this litigation is not about Dey's having reported prices at which substantial, or even some, sales were made. *Cf.* 16 C.F.R. § 233.3(d) (FTC Guidelines). The undisputed evidence shows that Dey reported AWPs bearing no economic relationship to any

actual sales prices.[9] These were not "list" prices; they were not "prices" at all in any meaningful sense of the word. They were, instead, concocted and reported solely to increase reimbursement. As such, no reasonable jury could conclude that Dey's AWPs were consistent with Medicare's statutory "reasonable charge" standard, 42 U.S.C. § 1395(l)(a)(2).

In the end, the absence of any indication of approval renders evidence of the government's emerging recognition of the unreliability of published AWPs irrelevant to Dey's liability under the FCA. *Accord New York v. Pharmacia Corp., et al.*, (N.Y. App. Div.) Apr. 26, 2007 Mem. and Order (appended as Exhibit 1) at 3 ("Because [New York's] claims do not depend upon an allegation that agencies or officials were deceived, but rather that respondents intentionally inflated the reported prices in order to manipulate and deceive the mandated statutory reimbursement formulae, any evidence that agencies or officials were aware of respondents' failure to provide prices actually paid would be neither necessary nor material to their defense."); *Walker v. Abbott Labs.*, CA No. CPM-L-682-01 (N.J. Super. Ct.) May 9, 2005 Mem. Decision at 4 (appended as Exhibit 2) (noting that key fact in context of government knowledge defense is whether government has indicated that the conduct at issue is "accepted and authorized").[10] Dey should not be allowed to introduce so-called government knowledge

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[9] Dey's expert, Dr. David Bradford, states in his report that the WACs and AWPs for Dey's drugs "have no economically or statistically meaningful relationship with one another because of the very different economic and institutional forces driving them." Bradford Rep., ¶ 90. Moreover, Dey has acknowledged in the course of AWP litigation that it reported AWPs for generic drugs that were based on published AWPs of corresponding brand drugs – abandoning any pretense of having set AWPs that corresponded to transaction prices of Dey's drugs.

[10] In *Walker*, the court accepted the assertions that (1) insurance companies and the government knew that AWPs were higher than acquisition costs, (2) AWP was the basis for reimbursement, (3) physicians were billing and being paid at AWP or an AWP-based formula, (4) insurance companies and the government "knew AWP was fictional," (5) physicians were making a profit from the difference between acquisition cost and AWP. Mem. Decision at 3. However, according to the court, the critical issue under

evidence when it cannot establish the relevance of such evidence to any determination the jury will need to make at trial.

**B. Nor Is the Evidence Relevant to Damages**

Dey's last resort is to argue that such evidence is relevant to damages; specifically, that evidence relating to the Medicare Modernization Act (MMA) legislation of 2004 (which went into effect *after* the Medicare damages period in this case) shows that Medicare would have paid a higher dispensing fee had defendants previously reported truthful prices and, therefore, that damages should be offset to account for the supposed "benefit" that Medicare received by virtue of defendants' inflated price reporting. That argument fails because it is wholly speculative and would confuse the jury.

In *Ward v. Dixie Nat. Life Ins. Co.*, 595 F.3d 164 (4th Cir. 2010), the Fourth Circuit upheld the exclusion of speculative damages evidence such as that proffered by Dey. In *Ward*, insureds sued defendant insurance companies to recover the difference between actual billed charges and the allowed amount paid to providers. Defendants argued that damages should be offset "by the higher insurance premiums that plaintiffs potentially would have paid" had defendants reimbursed actual charges. The Fourth Circuit rejected this argument, explaining that the "proposed damages offset is too largely in the realm of speculation." Quoting from the trial court's opinion, the Fourth Circuit noted that the increased premiums were "insufficiently certain" to justify offsetting damages:

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the causes of action pled in the case, even if the above facts were "readily apparent," was whether they were "accepted and authorized by the government and insurers." *Id.* at 4. Because defendants could produce no evidence of acceptance and authorization, they were "precluded from introducing any such evidence or testimony [respecting "insurer knowledge and government knowledge"] at trial." *See id.* and accompanying Order of May 9, 2005 (Exhibit 2).

> [T]he proposition that [defendants] can look back at their loss experience data, come up with how they would have increased their rates based on that loss experience data, proceed on the assumption that the South Carolina Department of Insurance would have approved the hypothetically requested rate increases [as is required by law], and alter the premium payments under these insurance contracts is . . . speculative.

595 F.3d at 182-83.

Here, there is no contemporaneous evidence that Medicare intended during the relevant time period that inflated AWPs would cross-subsidize inadequate dispensing fees. Evidence from as early as 1991 indicates that no dispensing fee was paid at all for Durable Medical Equipment ("DME") drugs at that time because the agency considered the costs of dispensing to be part of the overhead expense of the DME supplier, and therefore covered in the charge for the DME rental. *See* Exhibit 3 (at pp. AWQ046-0001 - 0002). Evidence concerning HCFA's establishment in 1994 of a $5.00 dispensing fee likewise contains no suggestion that the fee was set at that level because of some understanding that inflated drug reimbursement was cross-subsidizing dispensing costs. *See* Exhibit 4 (at AWQ074-0005), Exhibit 5 (AWQ074-0003), and Exhibit 6 (at AWQ074-0013). Defendants also cannot point to any competent evidence that in the decade between 1994 and 2004, HHS ever opted not to increase the $5.00 fee because of an awareness that dispensing costs were being cross-subsidized, or that the agency ever contemplated setting the dispensing fee in relation to anything other than dispensing costs.[11]

Congressional testimony offered by the Government Accountability Office ("GAO") in

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[11] The Balanced Budget Act of 1997, for example, contains no such discussion and simply included a provision authorizing the Secretary to pay a dispensing fee: "If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy." Pub. L. 105-33, 111 Stat. 462-463 (1997), § 4556, amending section 1842 of the Social Security Act (42 U.S.C. 1395u) to add a new subsection (o).

2001 illustrates the variety of factors driving decisions regarding the level of Medicare's dispensing fee. First, the testimony sets forth the GAO's understanding that HHS was overpaying not only for drugs, but also for the DME used to administer the drugs:

> For delivering pharmacy supplier-billed drugs, Medicare's payment policies are uneven. Pharmacy suppliers billing Medicare receive a dispensing fee for one drug type—inhalation therapy drugs—but there are no similar payments for other DME-administered or oral drugs. However, Medicare pays DME suppliers for the rental or purchase of equipment and supplies, and long-standing problems in the program's payments for these items may result in overpayments that implicitly compensate for some service delivery costs not covered.
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> * * *
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> Besides the profits on the DME-related drugs, pharmacy suppliers may receive additional compensation through the payment for DME and related supplies.

Testimony Before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, Statement of William J. Scanlon Director, Health Care Issues (Sept. 21, 2001) (GAO-01-1142T) at pp. 33, 37 (Exhibit 7). It is plain that multiple forms of overpayment – not just excessive drug reimbursement caused by inflated AWPs – were at play. The GAO's testimony highlights the perils of speculating, in hindsight, as to whether CMS would have raised the dispensing fee if Dey had reported accurate AWPs. Put simply, if Dey had acted lawfully, only one variable in the complicated calculus of Medicare reimbursement (drug reimbursement) would have changed, and it is sheer guesswork to try to quantify what effect, if any, this would have had on the other variables.

The only evidence defendants can point to in support of their argument that Medicare

damages should be offset to account for the cross-subsidization of dispensing fees lies in the 2004-2005 rulemaking proceedings. Those proceedings, however, were part of an entirely new legal regime, which came into effect *after* the relevant damages period. Moreover, the 2004-2005 rulemaking proceedings were based on new factual information. For example, CMS' interim dispensing fee for 2004-2005 was based on a study prepared by the American Association of Homecare ("AAH") evaluating levels of home health care service and related costs of dispensing *in 2004*. *See* 69 Fed. Reg. 66,236, 66,338 (Nov. 15, 2004) (Exhibit 8).[12] The rule establishing the final dispensing fees that took effect in 2006 was similarly based on information concerning levels of service and costs in 2003 (published in a 2005 OIG report) and 2004-2005 (based on another AAH report). *See* 70 Fed. Reg. 70,116, 70,226-70,228 (Nov. 21, 2005) (Exhibit 9).

In addition to being based on information post-dating the relevant time period, the post-MMA dispensing fee encompassed overhead and a variety of other expenses never contemplated in 1994 when the $5.00 fee was established. *Id*. Moreover, the MMA required reduction both to drug payments (by switching from AWPs to average sales prices (ASPs)) *and* to DME payments for the nebulizers used to administer these drugs.[13] Any guess as to the amount by which the

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[12] The AAH study was subsequently criticized. *See* HHS-OIG, *Review of Services Provided By Inhalation Drug Suppliers*, OEI-01-05-00090 (Sept. 2005); GAO, *Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs*, GAO–05–72 (Oct. 2004).

[13] Section 302(c) of the MMA amended Section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) to reduce payments for nebulizers by 22 percent, in response to findings by the HHS OIG that Medicare was over-paying for these items. See MMA Section 302(c)(2), amending 42 U.S.C. 1395m(a) to add a new subparagraph (21) (Exhibit 10 hereto) and referencing testimony of HHS OIG Inspector General Janet Rehnquist (see Exhibit 11 hereto). See also 69 Fed Reg. 47,488, 47,549 (Aug. 5, 2004) (Exhibit 12) (noting that section 302(c)(2) of the MMA "requires a reduction in Medicare payment, beginning with 2005, for specified items of DME, including nebulizers paid under code E0570.")

increase in dispensing fee was responsive to reduction in drug reimbursement versus that for DME reimbursement would be just that – a guess.

Nor can Dey find support in statements in post-MMA rulemaking proceedings in which CMS stated that a key purpose of the MMA legislation was "to eliminate cross subsidization of services."[14] The statements in the post-MMA rulemaking concerning the new dispensing fee indicate only that, by the time of the reforms of the MMA, inflated AWPs had given rise to *de facto* cross-subsidization, that the MMA sought to eliminate. The CMS statements do not in the least suggest that the agency or the Medicare program intended or encouraged cross-subsidization as evidenced by Congress's elimination of the problem in Title III of the MMA, entitled "Combating Waste, Fraud, and Abuse." Pub. L. 108-173, 117 Stat 2066 (Dec. 8, 2003). Accordingly, there is simply no permissible basis for admission of such evidence to support a theory that, had Dey reported accurate AWPs, HCFA in 1994 (or at any other time during the damages period) would have established a dispensing fee any different than it did, much less one comparable to the fee established for 2006.

In sum, there is no basis for admitting evidence of government knowledge for the purpose of calculating a possible damages offset based on legal changes made after the relevant damages period and premised on a different factual record and multiple concerns. As in *Ward v. Dixie Nat. Life Ins.*, in which, on a motion for summary judgment, the Court ruled that the testimony at issue was too speculative to create an issue for the jury, the evidence should be excluded here because it is not useful for determining anything the jury will need to decide.

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[14] 69 Fed. Reg. 66,236, 66,320 (Nov. 15, 2004) (Exhibit 8); *see also* 70 Fed. Reg. 70,116, 70,231 (Nov. 21, 2005).

Instead, the likely result of admitting such evidence would be to sow juror confusion by creating a bewildering array of *post hoc* and counterfactual hypotheses about what might have happened if Dey and all other drug manufacturers had followed the law, an exercise "too largely in the realm of speculation." *Ward*, 595 F.3d at 182; *see also John Morrell & Co. v. Local Union 304A, AFL-CIO*, 913 F.2d 544, 557 (8th Cir. 1990) (rejecting argument for a damages setoff to reflect labor savings during a strike where amount of the setoff was not proven with "reasonable certainty").

**CONCLUSION**

Dey cannot show that the "government knowledge" evidence is relevant to any element or defense of the FCA, or to damages. Such evidence has tremendous potential not only to confuse and mislead the jury, but also to encourage it to inrepret legislative intent and second-guess agency regulations. Accordingly, the Court should rule that such evidence is inadmissible at trial of the Medicare claims.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

Joyce R. Branda
Daniel R. Anderson
Laurie A. Oberembt
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
(202) 514-3345

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: /s/ *George B. Henderson, II*
George B. Henderson, II
Barbara Healy Smith
James J. Fauci
Assistant U.S. Attorneys
United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3272

FOR THE RELATOR,

James J. Breen
The Breen Law Firm, P.A.
5755 Northpoint Parkway, Suite 260
Alpharetta, GA 30022
Tel. (770) 740-000
fax: (954) 499-1173

Gary Azorsky
Susan Schneider Thomas
Roslyn G. Pollack
Berger & Montague, P.C.
1622 Locust St.
Philadelphia, PA 19103
(215) 875-3090

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ *George B. Henderson, II*
George B. Henderson, II
Assistant U.S. Attorney

Dated: June 10, 2010